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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,459	03/25/2004	Ivan Faul	1353-006	4841

61275 7590 08/04/2009

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EXAMINER	
FERNANDEZ, KATHERINE L	

ART UNIT	PAPER NUMBER
3768	

MAIL DATE	DELIVERY MODE
08/04/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/808,459	FAUL, IVAN	
	Examiner	Art Unit	
	KATHERINE L. FERNANDEZ	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14 and 17-20* is/are rejected.

7)☒ Claim(s) *15-16* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 September 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claim Objections

1. Claim 16 is objected to because of the following informalities:

Claim 16 recites the limitation "said wedge shaped members" in line 1. There is insufficient antecedent basis for this limitation in the claim. Examiner assumes claim 16 was intended to be dependent on claim 15.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1 and 3-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cosmon et al. (US Patent No. 6,122,541) in view of Ben-Haim et al. (US Patent No. 6,314,310) and further in view of Schulz et al. (US Patent No. 5,907,395) .

Cosmon et al. disclose a system for improving the accuracy of preprogrammed surgery on a body having an inside portion that is in need of said surgery and an outside portion that is moveable during said surgery, comprising: a plurality of markers, that are adapted to emit a corresponding plurality of signals, and that are adapted to be disposed on said moveable outside portion of said body proximate to said inside portion in need of said surgery (column 5, lines 23-31; column 11, lines 17-29); wherein said markers, respectively comprise a disposable support element, adapted to be attached to an outside portion of said body, and a signal emitter (i.e. LEDs) operatively

associated with said support element (column 5, lines 23-31; column 11, lines 16-29; column 11, line 31-column 12, line 28); wherein emitted signals are adapted to enable tracking the movement of said moveable outside portion of said body (column 5, lines 22-41; column 6, lines 20-58); means for tracking the movement of said outside portion of said body as a function of said emissions (column 5, lines 22-41; column 6, lines 20-58); means to identify and map said inside portion of said body that is intended to be subjected to surgery (column 3, lines 32-65; column 4, line 65-column 5, line 10); means to integrate said tracked movements with a treatment path to form a modified treatment path (i.e. path/position of probe is corrected by the reference markers, which track movement of said movable outside portion of said body) (column 4, line 59-column 5, line 22; column 6, line 59-column 7, line 22; column 13, line 9-29); and means to cause said treatment means to treat said inside portion of said body (column 4, line 59-column 5, line 22; column 6, line 59-column 7, line 22). The LEDs are disposed on a disposable support that is substantially unaffected by bodily excretions (column 11, lines 31-column 12, line 5). Their system further comprises receiver means (i.e. an array/plurality of cameras) (230,231) disposed remote from said body and positioned to be adapted to receive signals from said emitters, respectively (column 5, lines 23-31; column 4, lines 26-29). The emitters are in line of sight with said receiver means so that said signals emitted from said emitters are adapted to be received by said receiver means (column 5, lines 23-31; column 4, lines 26-29; see Figures 2). See Figure 2. With regards to claim 14, although Cosmon et al. do not specifically disclose that the LED's and said receiver are each disposed at an angle of about 45 degrees with respect

to the place where said body will be placed for said surgery, it would have been within the means of one of ordinary skill in the art to experimentally adjust the disposition of the LEDs and said receiver at angles with respect to the place where said body will be placed for said surgery in order to determine the disposition that most effectively allows emitted signals to be received by said receiver.

However, they do not specifically disclose a means for causing said emitters to respectively emit signals under conditions sufficient to differentiate which emitter is sending each of said signals, respectively, or that the treatment path is preprogrammed, and means to cause said treatment means to treat said inside portion of said body along said modified treatment path while substantially preventing said treatment means from departing from said modified treatment path to any substantial extent. They also do not specifically disclose that the treatment means is adapted to be operated without benefit of a surgeon. They further do not disclose that said LEDs are disposed remote from said body and further comprises at least one fiber optic cable having an end that is operatively associated with each of said LEDs at a location remote from said body and having another end that is adapted to be substantially fixedly disposed on said moveable outside portion of said body proximate to said inside portion of said body in need of said treatment. They further do not specifically disclose that the LED emissions are at least one selected from the group consisting of emissions having wavelengths in the visible red region and emissions having wavelengths in the infrared region. They further do not disclose that the emissions comprise visible wavelengths and optical fibers comprise plastic material.

Ben-Haim et al. disclose non-contact object location systems and position tracking of medical probes. They disclose that controls may be used to program a desired course (i.e. preprogrammed treatment path) that a needle is to follow (column 16, lines 40-54). The data is then displayed on an image to aid in alignment of a guide with the course and to track the progress of the needle along the course (column 16, lines 40-54). An audible alarm is issued if the needle deviates from the course by more than a predetermined tolerance and/or cues the surgeon as to the required course correction. Ben-Haim et al. further disclose that a computer may automatically control and adjust the guide to position a needle at an appropriate angle (i.e. needle adapted to be operated without benefit of a surgeon). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the system of Cosmon et al. to have the treatment path be preprogrammed and include means to cause said treatment means (which can be adapted to be operated without benefit of a surgeon) to treat inside portion of said body along said modified treatment path while substantially preventing said treatment means from departing from said modified treatment path to any substantial extent, as taught by Ben-Haim et al., in order to minimize errors and time spent by surgeon.

However, the above combined references do not specifically disclose a means for causing said emitters to respectively emit signals under conditions sufficient to differentiate which emitter is sending each of said signals, respectively. They further do not disclose that said LEDs are disposed remote from said body and further comprises at least one fiber optic cable having an end that is operatively associated with each of

said LEDs at a location remote from said body and having another end that is adapted to be substantially fixedly disposed on said moveable outside portion of said body proximate to said inside portion of said body in need of said treatment. They further do not specifically disclose that the LED emissions are at least one selected from the group consisting of emissions having wavelengths in the visible red region and emissions having wavelengths in the infrared region. They further do not disclose that the emissions comprise visible wavelengths and optical fibers comprise plastic material.

Schulz et al. disclose an effective way to produce substantially point source emissions of electromagnetic ray energy from locations on objects to be tracked in three dimensional space by an electro-optical location determination system (column 5, lines 18-23). They disclose that their emitters can be attached to any object being tracked, such as a patient (column 5, lines 35-48). Their invention consists of an optical fiber (24) having an emitter (26) attached at one end and a laser diode (20) (i.e. special type of LED) attached at the other end (column 6, lines 18-44; see Figure 2). The emitter end of the optical fiber is attached to the object (12) being tracked and the laser diode end is at a location remote from the object (column 6, lines 18-44; see Figure 2). Their invention further comprises an electro-optical sensor assembly (i.e. camera array) that senses the emission and returns raw data of the location of each emitter (column 7, lines 26-60; column 8, lines 9-20). The laser diodes can be located individually and uniquely identified (column 7, line 62-column 8, line 8; column 3, lines 33-49). The LED emissions can be either in the infrared region or can comprise visible wavelengths (column 3, lines 50-57; column 13, instant claims 27 and 28). They further disclose that

the optical fibers can be made of plastic (column 9, lines 5-7). Although they do not specifically disclose that the optical fibers can be made from glass, it is well known in the art that optical fibers can be made of glass and therefore it would have been within the skill of one of ordinary skill in the art to use a widely available and well known material, such as glass, for the optical fiber. As can be seen in Figure 1, the camera array (30) can be disposed remote from the object being tracked and positioned to receive signals from said emitters, respectively (column 8, lines 9-27). Their system includes means to control the frequency of emissions from said emitters at a rate such that changes in the location of said moving outside surface are reflected in the determined positions and orientations of said markers as a function of time (column 7, line 62-column 8, line 8). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of the above combined references to include the above discussed limitations, as the above combined references require marker means (i.e. LEDs) for tracking the movement of the outside portion of the body and Schulz et al. disclose a successful means for tracking an object by using optical fibers with LEDs (which emit signals sufficient to differentiate which emitter is sending each of said signals, respectively) attached to one end located remotely from the body and the other end attached to the object being tracked which provides a more accurate determination of the position and orientation of object being tracked (see abstract).

4. Claims 2 and 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cosmon et al. in view of Ben-Haim et al. and Schulz et al. as applied to claim 1 above, and further in view of Angulo (US Patent No. 4,474,180).

As discussed above, the above combined references meet the limitations of claim 1. Further, Schulz et al. disclose a means to control the frequency of emissions from said emitters at a rate such that changes in the location of said moving outside surface are reflected in the determined positions and orientations of said markers as a function of time (see Schulz et al., column 7, line 62-column 8, line 20) and means to at least frequently reintegrate the determined position and orientation of said outside portion of said body with the preprogrammed treatment path to form a modified treatment path such that said modified treatment path substantially accurately represents the changing real boundaries of a feature (see Cosmon et al., column 8, line 20-38). Cosmon et al. further disclose a treatment means that comprises of a surgical instrument, such as surgical tools, cutters, endoscopes, etc. However, they do not specifically disclose that the treatment means comprises high energy radiation sufficient to render said inside portion of said body necrotic, wherein treatment means comprises high energy ultrasound radiation and wherein said inside portion of said body comprises at least one stone in need of removal and further comprising said ultrasound radiation being of sufficient strength to be adapted to break up said stone into pieces that are small enough to be passed. Angulo discloses ultrasonic instrumentation for disintegrating urinary calculi or kidney stones (column 2, lines 1-5). Their ultrasonic instrument includes a wire probe connected to an ultrasonic transducer and which is fed through a catheter to the site of the kidney stone (column 2, lines 20-22). Vibrational energy (i.e. 20KHz in frequency) is induced in the wire probe necessary to shatter kidney stones (column 4, lines 38-50; column 1, lines 53-68). At the time of the

invention, it would have been obvious to one of ordinary skill in the art to modify the invention of the above combined references to have the treatment means comprise an ultrasonic instrument that comprises ultrasound radiation of sufficient strength to break up stones, as Cosmon et al. require a surgical tool and Angulo teaches an ultrasonic instrument capable of performing surgical actions, such as breaking up kidney stones (column 2, lines 1-5).

Allowable Subject Matter

5. Claims 15-16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: The prior art does not teach or suggest a system wherein emitters are operatively associated with wedge shaped members and wherein the combination of said emitters and said wedge shaped members, respectively, are adapted to dispose said emitters in line of sight with receiver means and the wedge shaped members have adjustable angles in combination with the other claimed elements.

Response to Arguments

6. Applicant's arguments with respect to claims 1-20 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE L. FERNANDEZ whose telephone number is (571)272-1957. The examiner can normally be reached on 8:30-5, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric F Winakur/
Primary Examiner, Art Unit 3768